RULES
OF
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

CHAPTER 1200-2-7
USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

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1200-2-7-.01 PURPOSE.

This Chapter establishes requirements for the use of sealed sources of radioactive material in the healing arts. The provisions of this Chapter are in addition to and not in substitution for other applicable provisions of these regulations.

Authority: *T.C.A. §68-28-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-2-7-.02 SCOPE.

Except as otherwise specifically provided, this Chapter applies to all persons who use sealed sources in the healing arts.

Authority: *T.C.A. §68-28-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-2-7-.03 INTERSTITIAL, INTRACAVITARY, AND SUPERFICIAL APPLICATIONS.

(1) Accountability, storage, and transit.

(a) Except as otherwise specifically authorized by the Division, every hospital, clinic or physician possessing sealed sources shall maintain a written accountability of the issue from storage and return to storage of all sealed sources. This record shall include but is not limited to the following information: dates, number of sealed sources, location of use, quantity of material in each sealed source and signature of individual(s) involved in each removal from and each return to storage.

(b) Every hospital, clinic or physician possessing sealed sources shall conduct a physical inventory at least quarterly to account for all sealed sources possessed by him. Records of the inventories shall be maintained for inspection by the Division and shall include the identity of the sealed sources, the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.

(c) When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to insure that provisions of 1200-2-5-.03, -21200-2-5-.06(1), and 1200-2-5-.07 are met.

(d) Each licensee shall follow the radiation safety and handling instructions approved by the Division, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing State and furnished by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form.

(e) Each licensee shall assure that needles or standard medical applicator cells containing cobalt 60 as wire, radium 226, or cesium 137 are not opened while in the licensee's possession unless specifically authorized by a license issued by the Division.

(2) Testing sealed sources for leakage and contamination.

(a) All sealed sources with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage prior to initial use and at intervals not to exceed six (6) months.

(b) If there is reason to suspect that a sealed source or device containing a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.

(c) The test required by (a) and (b) of this paragraph (2) shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours.[1]

(d) Any test conducted pursuant to 1200-2-7-.03(2)(a) and (b) which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The source shall be immediately withdrawn from use and decontaminated and repaired or disposed of in accordance with Division regulations. A report shall be filed within five (5) days of the test with the Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532, describing the equipment involved, the test results, and the corrective action taken.

(e) Leak tests results shall be recorded in units of microcuries and maintained for inspection by the Division.

(3) Radiation surveys.

(a) For patients to whom brachytherapy sealed sources have been applied, the maximum radiation level at a distance of 1 meter from the patient, or optionally at the bedside shall be determined by measurement or calculation and preferably by both. This radiation level shall be entered on the caution sign posted as required by 1200-2-7-.03(4).

(b) The radiation levels in the patient's room and the surrounding area shall be determined (by measurement or calculation), recorded, and maintained for inspection by the Division.

(c) The licensee shall assure that patients treated with cobalt 60, cesium 137, iridium 192, or radium 226 implants remain hospitalized until a source count and radiation survey of the patient confirm that all implants have been removed.

(4) Posting.

(a) In addition to the requirements of 1200-2-5-.12, the bed, cubicle, or room of the brachytherapy patient shall be posted with a sign indicating the presence of brachytherapy sealed sources. This sign shall incorporate the radiation symbol, and specify the radionuclide, the date, the activity, and the individual to contact for radiation safety instructions. The sign is not required provided the exception in 1200-2-5-.13(2) is met.

(b) The following information shall be included in the patient's chart:

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[1] *Assay methods for testing radium sources outlined in the appendix to ANSI Standard 44.2 are acceptable for this purpose.*

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1. The radionuclide administered, number of sources, activity in millicuries, and time and date of administration;

2. The radiation symbol, the exposure rate at 1 meter, and name of the individual who made the determination;

3. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under 1200-2-5-.03.

Authority: *T.C.A. §68-28-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-2-7-.04 TELETHERAPY.

(1) Equipment.

(a) The housing shall be so constructed that at 1 meter from the sealed source, the maximum *exposure* rate does not exceed 10 milliroentgens per hour when the beam control mechanism is in the "off" position. An acceptable method for determining compliance with this requirement is outlined in Section 4.22(a). in Report No. 33 of the National Council on Radiation Protection and Measurements (NCRP) issued February 1, 1968.

(b) For teletherapy equipment installed after the effective date of these regulations, the leakage radiation measured at 1 meter from the sealed source when the beam control mechanism is in the "on" position shall not exceed the larger of 1 roentgen per hour or 0.1 percent of the useful beam.

(c) Adjustable or removable beam-defining diaphragms shall allow transmission of not more than five (5) percent of the useful beam *exposure* rate.

(d) The beam control mechanism shall be of a positive design capable of acting in any position of the housing. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum of risk of exposure.

(e) The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.

(f) When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.

(g) The equipment shall be provided with a locking device to prevent unauthorized use.

(h) There shall be at the housing and at the control panel a warning device that plainly indicated whether the beam is "on" or "off".

(i) The control panel shall be provided with a timer that automatically terminates the exposure after a preset time.

(j) Teletherapy sealed sources shall be tested for leakage and contamination in accordance with the procedures described in 1200-2-7-.03(2) of this Chapter, except that tests of leakage may be made by wiping surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.

(k) The treatment room shall be so constructed that persons within the room may at all times be able to escape.

(l) Windows, mirror systems, or closed-circuit television shall be provided and shall be so located that both the patient and the control panel will be under observation at all times by the operator at his position at the control pane.

(2) Shielding.

(a) Primary barriers shall be provided for any area that the useful beam may strike when using the largest possible diaphragm opening. Such barriers shall extend at least 1 foot (30.5 centimeters) beyond the useful beam for any possible orientation.

(b) Secondary barriers shall be provided for all occupied areas exposed to leakage and scattered radiation.

(3) Operation. No individual who is occupationally exposed to radiation shall be in the treatment room during irradiation unless he is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.

(4) Calibration and spot-check measurements.

(a) Any licensee authorized to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit:

1. Prior to the first use of the unit for treating humans;

2. Prior to treating:

(i) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for physical decay;

(ii) Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one year.

(b) Full calibration measurement required by (a) of this paragraph shall include determination of:

1. The *exposure* rate or dose rate to an accuracy within) 3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;

2. The congruence between the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;

4. Timer accuracy; and

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5. The accuracy of all distance measuring devices used for treating humans.

(c) Full calibration measurements shall be made in accordance with the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Associated of Physicists in Medicine (Physics in Medicine and Biology, Vol. 16, No. 3, 1971, pp. 379-396).

(d) The *exposure* rate or dose rate values determined in (b)1 of this paragraph shall be corrected mathematically for physical decay for intervals not exceeding one month.

(e) Full calibration measurements required by (a) of this paragraph and physical decay corrections required by (d) of this paragraph shall be performed by a qualified expert as defined in 1200-2-4-.04(1)(pp).

(f) Any licensee authorized to use teletherapy units for treating humans shall cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month.

(g) Spot-check measurements required by (f) of this paragraph shall include determination of:

1. Timer accuracy;

2. The congruence between the radiation field and the field indicated by the light beam localizing device;

3. The accuracy of all distance measuring devices used for treating humans;

4. The exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions;

5. The difference between the measurement made in (g)4 of this subparagraph and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(h) Spot-check measurements required by (f) of this paragraph shall be performed in accordance with procedures established by a qualified expert. (A qualified expert need not actually perform the spot-check measurements). If a qualified expert does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 days.

(i) The licensee shall determine if a person is a qualified expert in accordance with the requirements of 1200-2-4-.04(1)(pp).

(5) Requirement to calibrate instruments used for calibration and spot-check measurements.

(a) Full calibration measurements required by paragraph (4) shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Associated of Physicists n Medicine. The dosimetry system shall have been calibrated within the previous two (2) years and after any servicing that may have affected system calibration.

(b) Spot-check measurements required by paragraph (4) shall be performed using a dosimetry system that has been calibrated in accordance with (a) of this paragraph. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with (a) of this paragraph. This alternative calibration method shall have been performed within the previous one (1) year

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and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

(6) Inspection and servicing of the source exposure mechanism.

(a) The licensee shall cause each teletherapy unit used to treat humans to be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) Inspection and servicing of the teletherapy unit shall be performed by persons specifically licensed to do so by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State.

(7) The licensee shall determine in accordance with 1200-2-4-.04(1)(pp) if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for (and review the results of) spot check measurements.

(8) Monitor and survey instruments.

(a) Each licensee authorized to use teletherapy units for treating humans shall install a permanent radiation monitor in each teletherapy room for continuous monitoring of beam status.

(b) Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that may result in an exposed or partially exposed source. The visible indicator of high radiation levels must be located so as to be observable by a person entering the treatment room.

(c) Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the teletherapy unit. This emergency power supply may be a battery system.

(d) Each radiation monitor must be tested for proper operation each day before the teletherapy unit is used for treatment of patients.

(e) If a radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a properly operating portable survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may have resulted in an exposed or partially exposed source. Survey instruments or dosimeters must be tested daily before use.

(9) Records. The licensee shall maintain, for inspection by the Division, records of the measurements, tests, corrective actions, inspection and servicing of the teletherapy unit, instrument calibrations and records of licensee's evaluation of the qualified expert's training and experience made under 1200-2-7-.04(4),(5),(7) or (8), as applicable.

Authority: *T.C.A. §§4-5-201 et seq., 68-28-101 et seq., and 68-202-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed July 18, 2002; effective October 1, 2002.*